REMARKS

The present Amendment is responsive to the Official Action mailed October 26, 2006. A petition for a three-month extension of the term for response to said Official Action, to and including April 26, 2007, is transmitted herewith.

The present Amendment is also intended to make of record the telephone interview between undersigned counsel and Examiner Peter Vrettakos on April 17, 2007. The Examiner's courtesy and cooperation in conducting the aforesaid interview are greatly appreciated.

Claims 7 and 9-10 are rejected under 35 U.S.C. § 102(e) on *Collins*, U.S. Patent No. 6,837,886 ("*Collins*"), or in the alternative, on *Natale*, U.S. Patent No. 6,764,486. Reconsideration and withdrawal of these rejections are respectfully requested.

In the interview, undersigned counsel pointed out that the teachings of *Collins et al.* at column 14, lines 64-67, cited in the Official Action as teaching a tubular structure for injection of the contrast medium, in fact, teach a tubular structure which terminates proximally of the ablation device when the ablation device is in an operative condition. Thus, the "longitudinal member 142," which may be a stainless steel hypotube, has its output or "opening 152" (FIG. 21) mounted on a sheath 144. The catheter 12 carrying the expandable ablation device is advanced through this sheath. (*See*, col.14 ll.40 *et seq.*) Counsel also pointed out the passage at column 8, lines 1-5, suggesting that the "tubular member 22" (FIGS. 4 and 5) may be a hollow tube which could carry a contrast medium, but noted that there was no indication in that passage of the reference as to where the opening, if any, of the hollow tube was positioned (*i.e.*, proximally or distally of the ablation device), or when the contract medium would be introduced.

In response, the Examiner cited the "irrigation system" (FIG. 18), and noted the passage at column 13, lines 13-21 as assertedly teaching introduction of a contrast medium through the irrigation system while the device is in an expanded condition. It is respectfully submitted that, even assuming that the irrigation system would be used in this manner, the teachings of the reference still do not meet claim 7 as amended.

In the interview, the Examiner questioned what was meant by "a distal side of the device" and explained that, considered broadly, a "distal side of the device" could be taken as any portion of the device lying more than half-way along the length of the catheter used to place the device, from its proximal end to its distal end. It is respectfully submitted that this broad construction is so broad as to be an unreasonable construction given the language of the claim reciting "providing an ablation device in a chamber of the heart . . . ." The "ablation device" manifestly is the device which performs the ablation, and not the introducer catheter. Additionally, claim 1 has been clarified to state that the device in its operative configuration has "opposite proximal and distal directions," and that the distal side of the device is the side "facing substantially in the distal direction toward a region of the wall of the chamber to be ablated." As used consistently throughout applicant's specification, the distal direction is the direction along the device away from the proximal end of the introducer catheter. Thus, the "distal side of the device" is the side facing in the direction along the structure, away from the proximal end of the introducer catheter.

Even given that construction, it is noted that a portion of the "irrigation system" (tubes 102 and ports 104) extends toward the distal end of the ablation device (to the

right in FIG. 18). For purposes of this response, it is believed unnecessary to determine whether the ablation device in *Collins* could be said to define a distal side, and whether some of the ports on the right-hand side of the drawing might arguably be said to lie on the distal side, so that contrast medium could be introduced through the ports on the distal side of the device. Even with that assumption, the *Collins* structure and its method of operation do not meet amended claim 7.

The claim explicitly recites providing the ablation device "in a chamber of the heart . . ." with the distal side facing "toward a region of the wall of the chamber to be ablated," injecting the contrast medium and "ablating the region of the wall of the chamber using the ablation device." *Collins'* device is used for ablation only inside a blood vessel. *See* col.3 ll.24-33. Thus, nothing in *Collins* has been pointed out as suggesting bringing the device to the condition shown in FIG. 18 while the device is inside a chamber of the heart, as distinguished from a blood vessel, so that any asserted distal side of the device faces toward some region of the chamber wall; or ablating the chamber wall using the device. The § 102 rejection of claims 7, 9 and 10 on *Collins* should be withdrawn.

The rejections of claims 83-88 as assertedly obvious over *Collins* should be withdrawn for the same reasons. Additionally, it is respectfully submitted that the treatment of claims 83-88 in this rejection does not fairly meet the burden of the Office to show that the claimed combination would be obvious. In particular, the allegation that the features recited in the text of these dependent claims constitute "obvious surgical steps" or "very basic surgical steps" is believed to be unsupported by any showing that the art would suggest these steps. The language from the M.P.E.P. concerning "optimization within prior art conditions or through routine experimentation" is believed to inapposite. The quoted passage

deals with optimization of percentages or numerical ranges of known result-effective variables in an existing process. Here, nothing in the prior art has been cited as showing that anyone had even contemplated injecting contrast medium into the subject "so that the medium advances forwardly into at least one pulmonary vein, and the medium is carried by blood flow back toward the ostium of the vein and into the chamber around the ablation device," as recited in the text of claim 83, in conjunction with the further requirement of "obtaining one or more images depicting the contrast medium in at least a portion of the chamber so as to visualize the position of the ablation device . . . ," as recited in claim 7 and incorporated by dependency in claim 83. These two passages in combination require that the device be disposed in the chamber of the heart, be imaged by contrast medium which is carried back into the heart from the pulmonary vein after first passing forwardly into the pulmonary vein. *See*, for example, ¶¶ 0061 and 0062 of the present specification for examples of this arrangement. Such an arrangement is believed to be impossible with *Collins*, inasmuch as the *Collins*' ablation device is disposed in pulmonary vein rather than in the chamber.

Claim 84 has now been amended to depend from claim 83 rather than from 10. Claims 84-87 thus further specify the method as including maintaining abutment with the heart wall in the vicinity of a pulmonary vein ostium while the contrast medium is injected, and subsequently retracting the device away from the heart wall after injecting the contrast medium to facilitate that flow of the contrast medium into the chamber (claim 86), and obtaining an image after this retracting step. *See* ¶ 0065 of the present specification for an example of this sequence of steps. Nothing in *Collins* has been pointed out as suggesting this specific sequence of steps for introducing contrast medium and obtaining images.

Claim 88, dependent from claim 10 recites that the method (including the ablation step now recited in claim 10) is performed "without forcibly engaging the structure with the wall of the pulmonary vein." This is believed to be in direct contrast with the features of *Collins*, which expands the basket-like device into a ring in abutment with the pulmonary vein. *See* FIG. 22 of the reference.

Claims 7, 9, and 10 were rejected as anticipated by *Natale*, whereas claims 83-88 were rejected as obvious over this reference under § 103. As discussed in the interview, the passage at column 2, lines 55-58 of *Natale*, referring to an "additional lumen for injecting an x-ray contrast medium" into the pulmonary vein "for angiographic imaging" does not say anything about when the contrast medium should be introduced. However, the passage at column 3, line 64 to column 4, line 4 is explicit. It instructs the artisan to first confirm the "correct position of the distal through the positioning catheter 2" inside the pulmonary vein and then inflate the balloon 4 so as to bring the ablation device to its operative condition. Thus, *Natale* teaches that location steps such as the use of contrast medium should be performed before the ablation device is brought to its operative condition. *Natale* thus fails to teach the step of injecting a contrast medium into the subject "while the ablation device is in said operative configuration" as recited in step (b) of present claim 7. Indeed, *Natale* leads directly away from such a step. *Natale*, therefore, does not anticipate the methods of claims 7, 9, and 10, and does not suggest or render obvious the methods of claims 83-88.

New claims 89-92 have been presented. These claims are believed to be supported by the disclosure in, *e.g.*, FIGS. 1 and 2, and the related text. As each of these claims depends directly or indirectly from claim 10, each of these claims is

believed to distinguish over the art of record for the reasons advanced above with respect to claims 7 and 10. Moreover, new claim 89 recites that the step of providing the device in an operative condition includes inflating a balloon within the chamber of the heart, and that the step of introducing contrast medium is performed so that the contrast medium is disposed outside of the balloon. This further distinguishes the claimed invention over *Collins*, which employs an expansible mesh-like device rather than a balloon.

New claims 90 and 91 are supported by paragraphs 0061 and 0063 of the specification, respectively. These claims specify introduction of the contrast medium either through a port in a wall of the balloon adjacent the central axis of the device (as exemplified in FIG. 1 and ¶ 0061 of the present specification), or through an outlet port of a tubular stylet communicating with the chamber of the heart adjacent the axis of the device (as exemplified in FIG. 2 and ¶ 0063 of the present specification). These claims further contrast with the newly-asserted irrigation structure in FIG. 18 of *Collins*.

New claim 92 specifies that a step of introducing contrast medium may be performed so that the contrast medium is injected "only on the distal side of the device." In *Collins*, any contrast medium introduced through the irrigation system of FIG. 18 would be injected on the proximal side of the device, as well as on any asserted distal side.

For the reasons set forth above, favorable reconsideration and allowance of all claims in the application as amended are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: April 23, 2007

Respectfully submitted,

By 

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